PA 1104641

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

December 15, 2003

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: *60/428,942*
FILING DATE: *November 26, 2002*

PRIORITY DOCUMENT
SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH
RULE 17.1(a) OR (b)

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

H. L. JACKSON
Certifying Officer

PTO/SB/16 (8-00)
Approved for use through 10/31/2002. OMB 0651-0032
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Docket Number	033136-354	Type a plus sign (+) inside this box +

INVENTOR(S)/APPLICANT(S)

Last Name	First Name	Middle Initial	Residence (City and either State or Foreign Country)
WORONA	Taras		Mississauga, Ontario, Canada

TITLE OF THE INVENTION (280 characters max)

BLOOD TREATMENT CONTROL SYSTEM

CORRESPONDENCE ADDRESS

BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, Virginia 22313-1404

21839

STATE	Virginia	ZIP CODE	22313-1404	COUNTRY	United States of America

ENCLOSED APPLICATION PARTS *(check all that apply)*

[X] Specification *Number of Pages* 25 [X] Drawing(s) *Number of Sheets* 8

[ ] Other (specify)

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT *(CHECK ONE)*

[X] Applicant claims small entity status. See 37 CFR § 1.27. [X] A check or money order is enclosed to cover the Provisional filing fees. [X] The Commissioner is hereby authorized to charge any deficiency in filing fees or credit any overpayment to Deposit Account Number 02-4800. This paper is submitted in duplicate.	PROVISIONAL FILING FEE AMOUNT(S)	$ [X] $80.00 (2005) $ [ ] $160.00 (1005)

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

[X] No.

[ ] Yes, the name of the U.S. Government agency and the Government contract number are:

Respectfully submitted,

SIGNATURE Matthew L Schneider Date November 26, 2002

TYPED or PRINTED NAME Matthew L. Schneider Registration No. 32,814 *(if appropriate)*

[ ] Additional inventors are being named on separately numbered sheets attached hereto

(10/02)

Patent
Attorney's Docket No. 033136-354

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
)
Taras WORONA)
)
Application No.: Unassigned)
)
Filed: November 26, 2002)
)
For: BLOOD TREATMENT)
CONTROL SYSTEM)

PROVISIONAL APPLICATION TRANSMITTAL LETTER

BOX PROVISIONAL PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This is a request for filing a Provisional Application for Patent Under 37 C.F.R. §1.53(c) without a Cover Sheet. Enclosed for filing is the provisional application for BLOOD TREATMENT CONTROL SYSTEM including:

[X] 25 pages of specification;

[X] 8 sheets of drawings; and

[ ] _____.

[X] Small entity status is hereby claimed.

A Cover Sheet for completion of the present provisional application will be subsequently filed together with a surcharge under 37 C.F.R. § 1.16(l) in accordance with 37 C.F.R. §1.53(g). Issuance of notification of the granting of a filing date under 37 C.F.R. §1.53(c) and notification of when the Cover Sheet is due to be filed in accordance with 37 C.F.R. §1.53(g) are requested.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: November 26, 2002

By: _____
Matthew L. Schneider
Registration No. 32,814

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

(10/02)

BLOOD TREATMENT CONTROL SYSTEM

BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

The present invention relates to the processing of blood, and more particularly to methods, devices and systems for reducing errors in the collection and delivery of blood to patients.

2. DESCRIPTION OF THE RELATED ART

The field of medicine has worked diligently over the years to improve the safety of blood collection and delivery in patient care. The consequences of an error, for example in delivering a blood sample to the wrong patient, can be serious, if not severe. A current technique uses a series of four identically numbered decals that are used to track the two syringes, the disposable and the patient during the blood treatment. The blood treatment involves:

1 Removing the blood from the patient to a syringe.

2 Transporting that syringe to a blood treatment disposable within which the treatment occurs.

3 Removing the treated blood from the disposable to the blood delivery syringe and

4 Returning the blood to the patient.

The serial number on the decals are compared to one another at each transfer step by the operator to ensure that the correct blood is tracked throughout the process to eventually ensure the correct blood is given to each patient.

At each comparison a decision is made and at each decision point there exists a potential for human error. For example, during quality control inspection the success rate for 100% inspections is generally understood to be approximately 80%.

An Intensive Care Unit (ICU) at a British hospital has gained recognition for its efforts to reduce errors in blood treatments. The system requires that a new patient entering a ward on the ICU receive a new wristband that contains the information of Date of Birth (DOB), Name, Hospital ID number and a 2D barcode that contains the same information as well as any allergies, blood type and medications that the patient is currently receiving. This information is also stored on the hospital database.

The ICU nurse can then order autologous or donated blood to be delivered to the ICU for the patient. The blood information is confirmed on the blood bank computer monitor and the correct blood is selected. New barcodes are printed and placed on those blood bags. The blood bags are delivered to the patient.

At the bedside, the blood bag barcode and patient barcode are scanned to see if the blood and patient match. If they match, the operator or nurse is granted approval to proceed with the transfusion. If the match is not made, the nurse is not provided with approval and is given a warning not to transfuse the blood. The barcode reader and printed labels facilitates a machine assisted blood matching.

Despite the advances that have been made in the blood treatment techniques, improvements are still needed.

SUMMARY OF THE INVENTION

In one of its aspects, the present invention provides a device for controlling the collection and delivery of blood, comprising a syringe-engaging portion, the syringe-engaging portion being operable in a release position to receive a syringe when the syringe is in a blood-containing configuration, the syringe-engaging portion being operable in a lock condition for locking the syringe therewith, and access control means for controlling the release and lock positions according to a blood transaction condition.

In one embodiment, the syringe-engaging portion has a side wall containing a cavity to receive the syringe.

The syringe is of the type having a body having a first end flange on one end thereof and a plunger slidably engaged with the body, the plunger having a second end flange on a remote end thereof, the cavity having a first formation to receive the first end flange.

In one embodiment, the access control means further comprises at least one barrier portion to extend at least partially across the cavity in the lock position. In one example, the access control means has a pair of barrier members with opposing free end regions, the barrier members being movable between an open position wherein the free ends are separated to permit the syringe to pass therebetween and a closed position wherein the free ends are positioned sufficiently close to one another to prevent the removal or the addition of the syringe from the cavity. The barrier members are pivotally coupled to the syringe-engaging portion .

In one embodiment, the device has a control portion, the syringe-engaging portion being removably attached to the control portion. Actuating means are mounted in the control portion and are releasably coupled to the barrier members for actuating the barrier members between the open and closed positions. In addition, a second lock means is provided for locking the syringe engaging portion with the control portion, for reasons which will be described herein below.

In one embodiment, the control portion includes a data transfer unit. The data transfer unit is operable to receive patient identification data representative of a subject patient and thereby to establish a first blood transaction condition, the control portion being operable in the first blood transaction condition to transfer the barrier members to the release position to receive a first syringe containing blood from the subject patient and to transfer the barrier members to the locked position to lock the first syringe in the cavity.

In one embodiment, the data transfer unit includes data transmitting means, data receiving means and data storage means for recording data received by the data receiving means. Either the data transmitting means, the data receiving means, or both, may each include a wired or wireless data port. The wireless data port may include, for example, a barcode reader, or an RF signal receiver.

In one embodiment, the data transfer unit is operable to transfer the patient identification data to a blood treatment unit and thereby to establish a second blood transaction condition, the control portion being operable in the second blood transaction condition to transfer the barrier members to the release position to release the first syringe to a first syringe station in the blood treatment unit.

In one embodiment, the data transfer unit is operable to receive treated blood identification data from the blood treatment unit, the data transfer unit also being operable to receive treated blood verification data from a second syringe containing treated blood from the subject patient and positioned at a second syringe station in the blood treatment unit, thereby to establish a third blood transaction condition, the control portion being operable in the third blood transaction condition to transfer the barrier members to the release position to receive the second syringe.

In this case, the second lock means is operable to release the syringe engaging portion at the end of a blood treatment procedure to permit the second syringe to be transported to the subject patient while still being positioned in the syringe engaging portion.

In one embodiment, the data transfer unit is operable to receive patient verification data to establish a fourth blood transaction condition, the control portion being operable in the fourth blood transaction condition to transfer the barrier members to the release position to release the second syringe. In one example, the release of the second syringe occurs by the unlocking of the second lock means to release the syringe engaging portion from the control portion.

In another of its aspects, there is provided a system for blood processing, comprising:

- a first syringe to receive a blood sample from a subject patient;

- a patient identifier attachable to the subject patient;

- a blood treatment unit;

- a syringe carrier for transferring the first syringe containing the blood sample to the blood treatment unit, the syringe carrier being operable in a release position to receive the first syringe when the first syringe is in a blood-containing configuration, the syringe carrier being operable in a lock position for locking the first syringe therewith, and access control means for controlling the release and lock positions to control access to the first syringe according to a blood sample transfer condition.

- a second syringe to receive the blood sample after treatment in the blood treatment unit to form a treated blood sample; and

-the syringe carrier being operable in the release position to receive the second syringe when the second syringe is in a blood-containing configuration, the syringe carrier being operable in the lock position for locking the second syringe therewith, said access control means being operable to controlling the release and lock positions to control access to the second syringe according to a treated blood transfer condition.

Preferably, the syringe carrier has provision to receive or record indicia indicative of a patients name or other patient identifying data, in manner readable to the operator or the patient or both. Preferably, the syringe carrier is also provided with a mechanism allowing the operator transfer the carrier to the release position to release the syringe.

In still another of its aspects, there is provided a method of controlling the transfer of blood between a subject patient and a blood treatment unit, comprising the steps of:

- providing a first syringe containing a sample of untreated blood from a subject patient;

- providing a syringe carrier which is operable in a release position to receive the first syringe; the syringe carrier being operable in a lock position for locking the first syringe therewith, the carrier having an access controller for controlling the release and lock positions according to a blood transaction condition, the access controller including a data transfer unit which is operable to receive patient identification data representative of a subject patient;

- in a first blood transaction step, delivering patient identification data representative of a subject patient to the data transfer unit, thereby to place the syringe carrier in a release position to receive the first syringe and thereafter to place the syringe carrier in a lock position to lock the first syringe therein;

- in a second blood transaction step , transferring the patient identification data to a blood treatment unit, thereby to place the syringe carrier in the release position to release the first syringe to a first syringe station in the blood treatment unit;

- in a third blood transaction step, delivering treated blood identification data from the blood treatment unit to the syringe carrier, and delivering treated blood verification data from a second syringe containing treated blood from the subject patient and which is positioned at a second syringe station in the blood treatment unit, and placing the syringe carrier in the release position to receive the second syringe; and

- in a fourth blood transaction step, delivering patient verification data to the syringe carrier and placing the syringe carrier in the release position to release the second syringe.

BRIEF DESCRIPTION OF THE DRAWINGS

Several preferred embodiments of the present invention will now be described, by way of example only,

with reference to the appended drawings in which:

Figure 1 is a perspective view of a system for blood processing system;

Figure 2 presents several views of several components of the system of figure 1;

Figure 3 presents several views of a component of the system of figure 1;

Figure 4 presents several operational views of the component of figure 3;

Figure 5 presents several other views of the component of figure 3;

Figure 6 presents still other views of the component of figure 3;

Figure 7 shows several assembly views of the component of figure 3; and

Figure 8 shows several perspective views of two components of the system of figure 1.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to figure 1, there is provided a system 10 for blood processing and which is based on the control of both the collection from and the delivery of blood to a patient. The system 10 includes a syringe carrier 12 which controls the transfer of a blood sample contained in a syringe, between the patient and a blood treatment unit 14. As will be described, the system is predicated on the concept that the administration of the technique can, in one embodiment, be governed by the syringe carrier 12 which serves as a key to the blood treatment unit 14. In other words, any attempt to avoid using the syringe carrier 12 will render the system 10 inoperable. The syringe carrier 12 is capable of receiving data to verify the identity of a subject patient and the blood sample at predetermined states of a blood treatment and then to lock, within its grasp,

a syringe containing blood, either untreated or treated, from or to the subject patient, in a manner which renders the syringe inaccessible and inoperable until proper verification has been made. However, the syringe carrier is not necessary in all cases. One embodiment discussed below provides for a secure method of verifying the patient and the blood during the blood treatment by the use of RF ID tags on a wristband and two syringes, wherein the wristband includes an RF reader and an RF writer.

Referring to figure 3, the syringe carrier 12 has a syringe-engaging portion 20 which is operable in a release position to receive the first blood sample-containing syringe 26 when the syringe is in a blood-containing configuration. The syringe-engaging portion is operable in a lock condition for locking the first syringe 26 therewith. The syringe carrier 12 has, as will be explained, an access control means for controlling the release and lock positions according to a blood transaction condition.

The syringe-engaging portion 20 has a side wall 22 containing a cavity 24 to receive the first syringe 26, the latter having a body 26a with a first end flange 26b on one end thereof and a plunger 26c slidably engaged with the body 26a and having a second end flange 26d on a remote end thereof. In this case, the cavity 24 has a first formation 24a to receive the first end flange 26b and a second formation 24b to receive the second end flange 26d.

The first formation 24a is dimensioned so that it closely approximates the outer profile of the first end flange 26b, while the second formation 24b is in the form of a rear end wall which is shaped to shield the second end flange 26b from being inadvertently contacted by an obstruction. Thus, when the syringe is placed in the cavity, the plunger 26c is less likely to be unintentionally depressed relative to the body 26a, to cause an unwanted dispensing of blood from the syringe, while in the syringe carrier 12. Alternatively, the second formation 24b may be arranged to engage the second flange 24b so that the plunger cannot be moved relative to the body, thereby causing both the plunger and the body to be held in position, thereby preventing the syringe 26 from being removed from the syringe carrier 12 and preventing the blood sample from being dispensed from the first syringe 26 while in the syringe carrier 12.

Referring to figure 3, the access control means includes a pair of barrier members 28 with opposing free ends 28a. The barrier members 28 are movable between an open release position wherein the free ends 28a are sufficiently separated to permit the syringe 26 to pass therebetween and a lock position wherein the free ends 28a extend toward one another at least partially across the cavity to prevent removal of the syringe 26 from the cavity. In this case, the barrier members 28 aré arcuate in shape and are pivotally coupled to the syringe-engaging portion near opposite sides of the cavity 24, but may also be pivotally or otherwise mounted.

The barriers 28 are, in this case, spring biased toward the locked position. This means that even if the syringe carrier is in an unlocked position, the barrier members 28 will retain the syringe in the cavity until needed, at which time the syringe may simply be grasped from the carrier and removed therefrom.

Referring to figures 5 and 7, the syringe-engaging portion 20 is removably attached to a control portion 34. Actuating means, in the form of solenoid activated links 36, are mounted in the control portion 20 and are releasably coupled to the barrier members 28 which engage an inner region 28b of the barrier members for actuating the barrier members 28 between the release and lock positions. Thus, the coupling of the links 36 to the barrier members 28 is made when the syringe-engaging portion 20 is attached to the control portion 34. This attachment, if desired, may also be configured so that the syringe-engaging portion 20 must remain with the control portion during the blood treatment process, so that any unauthorized removal of the syringe-engaging portion may, for example, lock the first syringe in the syringe-engaging portion.

The system is also provided with a wristband 38 (shown in figure 1) which contains a barcode that shares a common data component with the first syringe 26, so that each can be linked with a common patient. The barcodes on the wristband and first syringe 26 may also each include an additional data component, respectively identifying each as such. The wristband 38 and the first syringe 26 also include an area or location to receive indicia in printed or written form, in a manual or automated manner, identifying the patient with such information as the patient's name, data of birth and the like in a manner readable to both an operator and a patient, so that a patient, for example, may be located in a busy waiting room

Referring to figure 7, the control portion 34 includes a data transfer unit 40. The data transfer unit 40 includes data receiving means 42 in the form of a barcode reader and data storage means 44 in the form of a memory chip or the like for recording and storing data received by the data receiving means. The data receiving means 42 may include a wired or wireless data port. The wireless data port may include, as an alternative, an RF or Infrared signal transmitter or receiver, for example.

The data transfer unit 40 is operable to receive patient identification data representative of a subject patient and thereby to establish a first blood transaction condition, namely by scanning the patient's wristband 38 with the barcode reader 42. The control portion 34 is operable in the first blood transaction condition to transfer the barrier members to the release position to receive the first syringe 26 containing blood from the subject patient and to transfer the barrier members to the lock position to lock the first syringe 26 in the cavity.

Referring to figure 1, the blood treatment unit 14 has an access port 48, in the form of a drawer on the front face of the unit, which may be opened to expose an inner blood sample receiving area. A syringe platform 50 is provided to position the first syringe in the inner sample receiving area. Preferably, the syringe platform 50 is disposable and forms part of a blood treatment package as will be described. The syringe platform 50 has a first syringe station 52 to receive the first syringe 26 and a second station 54 to receive a second syringe 60 as will be described herein below. The syringe platform 50 is further provided with anchor means for anchoring the first and second syringes thereto, in the form of upstanding anchor tabs 56, as shown in figure 8.

The blood treatment unit 14 includes a syringe carrier docking bay at 64 as shown in figures 1 and 2, which receives the syringe carrier 12 following its release of the first syringe 26. The docking bay 64 includes a data port to be coupled with a complementary port 62 (shown in figure 3) in the housing of the control portion 34 to establish a data link between the data transfer unit 40 and a control system within the blood treatment unit 14. The data link between the syringe carrier 12 and the treatment unit may, alternatively, be wireless and use for example, the protocols mentioned below.

The data transfer unit 40 is operable to transfer the patient identification data to the blood treatment unit 14 and thereby to establish a second blood transaction condition, in which the control portion is operable in the second blood transaction condition to transfer the barrier members to the release position to release the first syringe 26 to the first syringe station 52.

The data transfer unit 40 is also operable to receive treated blood sample identification data from the blood treatment unit 14, while the syringe carrier 12 is positioned in the docking bay 64. The data transfer unit 40 is also operable to receive treated blood verification data from a second syringe containing treated blood from the subject patient and positioned at a second syringe station 54 in the platform 50, thereby to establish a third blood transaction condition. In this case, the barcode reader 42 may be used to scan a barcode located on the second syringe 60. The control portion is operable in this third blood transaction condition to transfer the barrier members 28 to the open position to receive the second syringe.

The data transfer unit 40 is operable to receive patient verification data such as by using the barcode reader 42 to scan a barcode on the patient's wristband to establish a fourth blood transaction condition. The control portion is operable in the fourth blood transaction condition to release the syringe engaging portion 20 from the control portion 34, thereby permitting the operator to carry the second syringe conveniently in the syringe engaging portion 20 to the patient. Alternatively, if desired, the control portion may be operable in the fourth blood transfer condition to transfer the barrier members to the release position to release the second syringe.

The control portion 34 includes a controller to control the functions of the syringe carrier 12 under the control of a number of preset instructions provided to the control portion 34 by a key pad having one or more buttons, such as that shown at 70 with a single button, located on an external portion of its housing, as shown in figure 6. Alternatively, the controller may be responsive to the data being received by the barcode reader which may include specific operational instructions. Alternatively, the data received by the barcode reader may initiate a preset sequence of events where the sequence includes one or more of the

blood transaction conditions as described above.

The control portion 34 may include a programmed logic controller or some other form of controller. It may be included in a software program configured to run on a general purpose computer, such as personal computer, or on a more substantial computer mainframe. The control portion 34 may include a computer which is operable to work within a network, for example so that the syringe carrier can be remotely programmed and its collected data uploaded to a central database. The network may thus involve several general purpose computers, for example those sold under the trade names APPLE™ or IBM ™, or clones thereof, which are programmed with operating systems known by the trade names WINDOWS™, LINUX or other well known or lesser known equivalents of these. The system may involve pre-programmed software using a number of possible languages or a custom designed version of a programming software sold under the trade name ACCESS™ or similar programming software. The computer network may be a wired local area network, or a wide area network such as the Internet, or a combination of the two, with or without added security, authentication protocols, or under "peer-to-peer" or "client-server" or other networking architectures. The network may also be a wireless network or a combination of wired and wireless networks. The wireless network may operate under frequencies such as those dubbed 'radio frequency' or "RF" using protocols such as the 802.11, TCP/IP, BLUE TOOTH and the like, or other well known Internet, wireless, satellite or cell packet protocols. The control function of the control portion 23 may, alternatively, be executed on a single custom built computer which is dedicated to the function of the system alone.

The system may be used in the following manner to control the transfer of blood between a subject patient and the blood treatment unit 14.

A first package is prepared including the patient wristband 38 and the first "blood retrieval" syringe 26 . If desired, the first package may also include a disposable or reusable syringe engaging portion 20. A second package may also be prepared including the syringe platform 50 and a second "blood delivery" syringe 60. If desired, both the first and second packages may be prepared in advance with the second

syringe 60 locked on the second station 54 of the syringe platform 50, in which the second syringe 60 may only be removed by the syringe carrier 12 during the blood treatment process as will be described.

The first "blood retrieval" syringe 26 contains a barcode similar to the wristband 38 but different enough from the wristband to be acknowledged as such. In other words, both the wristband 38 and the first syringe 26 are provided with a common or generic data component, while the wristband contains a unique data component identifying it as a wristband and the first syringe contains a unique data component identifying it as a first syringe. The second "blood delivery" syringe 60 is fitted with a separate unrelated barcode. Further, a human readable name matching system is also used to follow a blood sample through the steps of the treatment. In other words, the wristband 38 and first syringe 26 are each provided with a label where the patient's name can be added as indicia recognizable to the operator conducting the treatment. The syringe carrier 12 is provided to take control of the delivery of the blood samples to the treatment device and then return to the patient.

The procedure begins with blood being drawn into the first syringe 26, following a previous treatment with sodium citrate, and then the first syringe 26 is capped. The syringe engaging portion 20 is attached to the control portion 34 of the syringe carrier 12, before or after which the syringe carrier 12 is activated and the barcode on the wristband is scanned with the barcode reader. Since the wristband 38 and the first syringe 26 have a common data component, it may be sufficient simply to scan the wristband 38, though the first syringe 26 may also be scanned, if required, for further verification.

As a result, the syringe carrier 12 now has, within its memory, the common data component read by the barcode reader 42. The syringe carrier 12 then unlocks the barrier members and the filled syringe is then positioned in the cavity by spreading apart the now unlocked inwardly syringe biased barrier members 28, with the first and second end flanges in their corresponding first and second formations. The syringe carrier 12 is then activated and the barrier members are actuated to their lock positions to lock the first syringe 26 in place, thus signifying that the first blood transaction condition has been met.

The syringe carrier 12 is then positioned adjacent the platform 50 so that the first syringe 26 can be delivered to the first station 52 thereon and held by the anchor tabs 56 using a sliding action.

Now free of the first syringe 26, the syringe carrier 12 is installed in the syringe carrier docking bay 64 and then transfers patient identification data thereto over the data link which is established between the syringe carrier 12 and the blood treatment unit 14. The blood treatment unit 14 then proceeds to carry out a designed blood treatment on the blood sample and, thereafter, delivers the treated blood to the second syringe 60 already positioned in the second station 54 of the platform 50. The second syringe 60 has its own barcode containing a unique data component, which is unrelated to the common data component in the barcode of the first syringe 26 and the wristband 38. The treatment unit then reads the barcode on the second syringe 60 and transfers the treated blood sample identification data contained in the barcode to the syringe carrier 12 through the data transfer port 64. Then, the syringe carrier is positioned so that the barcode reader can scan the treated sample identification on the second syringe 60 to confirm a match, at which point the barrier members 28 are released and the second syringe 60 is transferred from the second station 54 in the platform 50 to the cavity and held therein by the barriers 28 in the lock position.

The syringe carrier 12 is then returned to the patient where the barcode reader is scanned over the wristband 38 to confirm a match between the treated blood sample and the subject patient. With the match established, the barrier members 28 may be transferred to their release position and the second syringe removed so that the treated blood may be delivered to the patient, to complete the process.

Thus, the data contained in the barcode and written or printed on the labels of the wristband 38 and the syringes are used to match and track the patient and the blood sample. The wristband contains the subject patient's name and Barcode ID. The syringe carrier 12 obtains and contains the barcode matching information as well as the written or printed patient name information thereon and the operator uses the barcode reader as a secondary matching device.

THE RF ID-ASSISTED TRACKING WITH NAME LABEL

In this example, the subject patient is fitted with a disposable RF ID scanner on his wrist and the first and

second syringes are equipped with RF ID chips within them. Written or printed name labels would still be affixed on the wristband as well as the first and second syringes.

The treatment would proceed as before, except that the syringe carrier does not function to lock the first or second syringes in place. Rather, the verification function occurs between the wristband, the first syringe, the treatment unit and the second syringe.

The RF ID treatment procedure is proposed as follows. First, the wristband and the first blood retrieval syringe are arranged so that each emits a common RF signal. The patient name and date of birth are written on the wristband as well as on the first and second syringes. A blood sample is then drawn from the patient using the first syringe and the wristband is attached to the wrist of the subject patient.

The syringe is delivered to the first station of the platform which is now in position in the treatment unit. At this point, the second delivery syringe is already installed in the second station of the platform. The treatment occurs where the treated blood sample is injected into the second delivery syringe. The treatment unit reads the RF ID on the first syringe and writes that ID onto the RF Tag of the second delivery syringe. This process of ID writing may only be done once, with current RF ID chips, though other devices may be available to make the writing process repeatable

The treatment is completed and the treatment unit opens to deliver a platform with an attached and empty first syringe and the attached second syringe containing the now treated blood sample. The second syringe is removed from the platform in the access port and is then transported to the patient. The patient is identified by name using the patient label on the second syringe.

The operator confirms the subject patient's identification by attempting to match RF ID data in the syringe with that contained in the patient's wristband by placing them in close proximity to one another. The wristband RF ID reader will emit a signal to confirm the match. The signal may be a sound or light emission, such as from a signal generator, an LED or the like.

The treated blood is then delivered to the patient. The wristband is removed from the patient and is taken to the treatment unit to close the audit trail and confirm that the treatment was completed.

THE RF ID ASSISTED TRACKING WITHOUT NAME LABEL

In this case, the RF ID based treatment procedure is as follows. First, a package is prepared containing a wristband, syringe carrier and first blood retrieval syringe. The wristband and the blood retrieval syringe have the same factory-installed and matching RF ID's. The patient's name and date of birth are written on the wristband and on a label provided on the syringe carrier.

The first syringe is used to draw a blood sample from the subject patient. The wristband is attached to the subject patient.

The syringe carrier is used, as before, to deliver the blood to the first station on the platform which is carrying the second syringe in the second station and the platform is itself located in the blood sample receiving area in the access port 48. The treatment unit is then activated to conduct a designated treatment on the blood sample. Thereafter, the treated blood is delivered to the second syringe.

The treatment unit reads the RF ID on the first syringe and writes that ID onto the RF ID of the second syringe. With the treatment completed, the treatment unit opens to deliver the platform with the two syringes. The operator manipulates the syringe carrier to transfer the barriers to the release position and then fixes the second syringe in the cavity, then transfers the barrier members to the lock position, then removes the second syringe from the disposable. The syringe carrier is then taken to the patient, as identified by the information contained on the syringe carrier label.

The operator confirms the patient's identification by attempting to match the second syringe's RF ID to the wristband RF ID by placing them in close proximity to one another. The wristband RF ID reader will emit

a signal, such as a beep and/or a light pulse, a signal over a wired or wireless data network, or the like to confirm a match, at which point the syringe carrier may be activated to transfer the barrier members to the release position so that the second syringe may be removed and the treated blood sample administered to the patient.

The wristband is removed from the patient and is taken to the treatment unit to close the audit trail and confirm that the treatment was completed.

While the present invention has been described for what are presently considered the preferred embodiments, the invention is not so limited. To the contrary, the invention is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the appended claims. The scope of the following claims is to be accorded the broadest interpretation so as to encompass all such modifications and equivalent structures and functions.

While the syringe carrier 12 uses barrier members 28 which physically grasp or block the first and second syringes in the cavity, other forms of barriers may be employed, such as those utilizing other physical barrier arrangements or non-physical barrier arrangements. For example, the barrier may be provided as an electromagnet to clamp the syringe in the cavity by way of a magnet coupling with a ferromagnetic band on the syringe body.

CLAIMS:

1. A device for controlling the collection and delivery of blood, comprising a syringe-engaging portion, the syringe-engaging portion being operable in a release position to receive a syringe when the syringe is in a blood-containing configuration, the syringe-engaging portion being operable in a lock condition for locking the syringe therewith, and access control means for controlling the release and lock positions according to a blood transaction condition.

2. A device as defined in claim 1 wherein the syringe-engaging portion includes a cavity to receive the syringe.

3. A device as defined in claim 2 wherein the syringe-engaging portion has a side wall and the cavity is located in the side wall.

4. A device as defined in claim 3 wherein the first syringe has a body having a first end flange on one end thereof and a plunger slidably engaged with the body, the plunger having a second end flange on a remote end thereof, the cavity having a first formation to receive the first end flange.

5. A device as defined in claim 2, wherein the access control means further comprises at least one barrier portion to extend at least partially across the cavity in the lock position.

6. A device as defined in claim 5 wherein the access control means further comprises a pair of barrier members with opposing free end regions, the barrier members being movable between an open position wherein the free ends are separated to permit the syringe to pass therebetween and a closed position wherein the free ends are positioned sufficiently close to one another to prevent removal of the syringe from the cavity.

7. A device as defined in claim 6, further comprising a control portion, the syringe-engaging portion being removably attached to the control portion.

8. A device as defined in claim 7, wherein the barrier members are pivotally coupled to the syringe-engaging portion near opposite sides of the cavity.

9. A device as defined in claim 8, further comprising actuating means mounted in the control portion and releasably coupled to the barrier members for actuating the barrier members between the open and closed positions.

10. A device as defined in claim 7 wherein the control portion includes a data transfer unit, the data transfer unit being operable to transmit and receive patient identification data representative of a subject patient and thereby to establish a first blood transaction condition, the control portion being operable in the first blood transaction condition to transfer the barrier members to the release position to receive a first syringe containing blood from the subject patient and to transfer the barrier members to the lock position to lock the first syringe in the cavity.

11. A device as defined in claim 10 wherein the data transfer unit includes data transmitting and receiving means and data storage means for recording data received by the data receiving means.

12. A device as defined in claim 11 wherein the data receiving means includes a wired or wireless data port.

13. A device as defined in claim 12 wherein the wireless data port includes a barcode reader, an RF signal receiver or an Infrared transmitter receiver.

14. A device as defined in claim 10 wherein the data transfer unit is operable to transfer the patient identification data to a blood treatment unit and thereby to establish a second blood transaction

condition, the control portion being operable in the second blood transaction condition to transfer the barrier members to the release position to release the first syringe to a first syringe station in the blood treatment unit.

15. A device as defined in claim 14 wherein the data transfer unit is operable to receive treated blood identification data from the blood treatment unit, the data transfer unit also being operable to receive treated blood verification data from a second syringe containing treated blood from the subject patient and positioned at a second syringe station in the blood treatment unit, thereby to establish a third blood transaction condition, the control portion being operable in the third blood transaction condition to transfer the barrier members to the release position to receive the second syringe.

16. A device as defined in claim 15 wherein the data transfer unit is operable to receive patient verification data to establish a fourth blood transaction condition, the control portion being operable in the fourth blood transaction condition to transfer the barrier members to the release position to release the second syringe.

17. A system for blood processing, comprising:

- a first syringe to receive a blood sample from a subject patient;

- a patient identifier attachable to the subject patient;

- a blood treatment unit;

- a syringe carrier for transferring the first syringe containing the blood sample to the blood treatment unit, the syringe carrier being operable in a release position to receive the first syringe when the first syringe is in a blood-containing configuration, the syringe carrier being

operable in a lock position for locking the first syringe therewith, and access control means for controlling the release and lock positions to control access to the first syringe according to a blood sample transfer condition.

- a second syringe to receive the blood sample after treatment in the blood treatment unit to form a treated blood sample; and

-the syringe carrier being operable in the release position to receive the second syringe when the second syringe is in a blood-containing configuration, the syringe carrier being operable in the lock position for locking the second syringe therewith, said access control means being operable to controlling the release and lock positions to control access to the second syringe according to a treated blood transfer condition.

18. A system as defined in claim 17 wherein the patient identifier includes a patient wristband.

19. A system as defined in claim 17, wherein the syringe carrier includes a syringe-engaging portion with a cavity to receive the syringe.

20. A system as defined in claim 19 wherein the syringe-engaging portion has a side wall and the cavity is formed in the side wall.

21. A system as defined in claim 20 wherein the first syringe has a body having a first end flange on one end thereof and a plunger slidably engaged with the body, the plunger having a second end flange on a remote end thereof, the cavity having a first formation to receive the first end flange.

22. A system as defined in claim 21 wherein the access control means further comprises at least one barrier portion to extend at least partially across the cavity in the lock condition.

23. A system as defined in claim 22 wherein the access control means further comprises a pair of barrier members with opposing free end regions, the barrier members being movable between an open position wherein the free ends are separated to permit the first or second syringes to pass therebetween and a closed position wherein the free ends are positioned sufficiently close to one another to prevent removal of the syringe from the cavity.

24. A system as defined in claim 23, wherein the syringe carrier further comprises a control portion, the syringe-engaging portion being removably attached to the control portion.

25. A system as defined in claim 24, wherein the barrier members are pivotally coupled to the syringe-engaging portion near opposite sides of the cavity.

26. A system as defined in claim 25, further comprising actuating means for actuating the barrier members between the open and closed positions.

27. A system as defined in claim 26 wherein the control portion includes a data transfer unit, the data transfer unit being operable to transmit and receive patient identification data representative of a subject patient and thereby to establish an untreated blood sample transfer condition, the control portion being operable in the untreated blood sample transfer condition to transfer the barrier members to the release position to receive the first syringe containing blood from the subject patient and to transfer the barrier members to the lock position to lock the first syringe therein.

28. A system as defined in claim 27 wherein the data transfer unit includes data receiving means and data storage means for recording data received by the data receiving means.

29. A system as defined in claim 28 wherein the data receiving means includes a wired or wireless data port.

30. A system as defined in claim 29 wherein the wireless data port includes a barcode reader or an RF signal receiver.

31. A system as defined in claim 28 wherein the data transfer unit is operable to receive treated blood identification data from the blood treatment unit, the data transfer unit also being operable to receive treated blood verification data from the second syringe containing treated blood from the subject patient and positioned at a second syringe station in the blood treatment unit, thereby to establish a treated blood transfer condition, the control portion being operable in the treated blood transfer condition to transfer the barrier members to the release position to receive the second syringe and to transfer the barrier members to the lock position to lock the first syringe therein.

32. A system as defined in claim 17, wherein the treatment unit includes a housing, further comprising a syringe platform removably mounted in the housing, the platform further comprising a first syringe station to receive the first syringe and a second syringe station to receive the second syringe.

33. A system as defined in claim 33 wherein the syringe platform further comprises an anchor means for anchoring the first and second syringes at the first and second syringe stations respectively.

34. A system as defined in claim 32 wherein each anchor means includes a pair of upstanding anchor tabs which engage the first end flange on the first syringe.

35. A method of controlling the transfer of blood between a subject patient and a blood treatment unit, comprising the steps of:

- providing a first syringe containing a sample of untreated blood from a subject patient;

- providing a syringe carrier which is operable in a release position to receive the first

syringe; the syringe carrier being operable in a lock position for locking the first syringe therewith, the carrier having an access controller for controlling the release and lock positions according to a blood transaction condition, the access controller including a data transfer unit which is operable to receive patient identification data representative of a subject patient;

- in a first blood transaction step, delivering patient identification data representative of a subject patient to the data transfer unit, thereby to place the syringe carrier in a release position to receive the first syringe and thereafter to place the syringe carrier in a lock position to lock the first syringe therein;

- in a second blood transaction condition, transferring the patient identification data to a blood treatment unit, thereby to place the syringe carrier in the release position to release the first syringe to a first syringe station in the blood treatment unit;

- in a third blood transaction step, delivering treated blood identification data from the blood treatment unit to the syringe carrier, and delivering treated blood verification data from a second syringe containing treated blood from the subject patient and which is positioned at a second syringe station in the blood treatment unit, and placing the syringe carrier in the release position to receive the second syringe;

- in a fourth blood transaction step, delivering patient verification data to the syringe carrier and placing the syringe carrier in the release position to release the second syringe.

ABSTRACT

A device for controlling the collection and delivery of blood, comprising a syringe-engaging portion, the syringe-engaging portion being operable in a release position to receive a syringe when the syringe is in a blood-containing configuration, the syringe-engaging portion being operable in a lock condition for locking the syringe therewith, and access control means for controlling the release and lock positions according to a blood transaction condition.

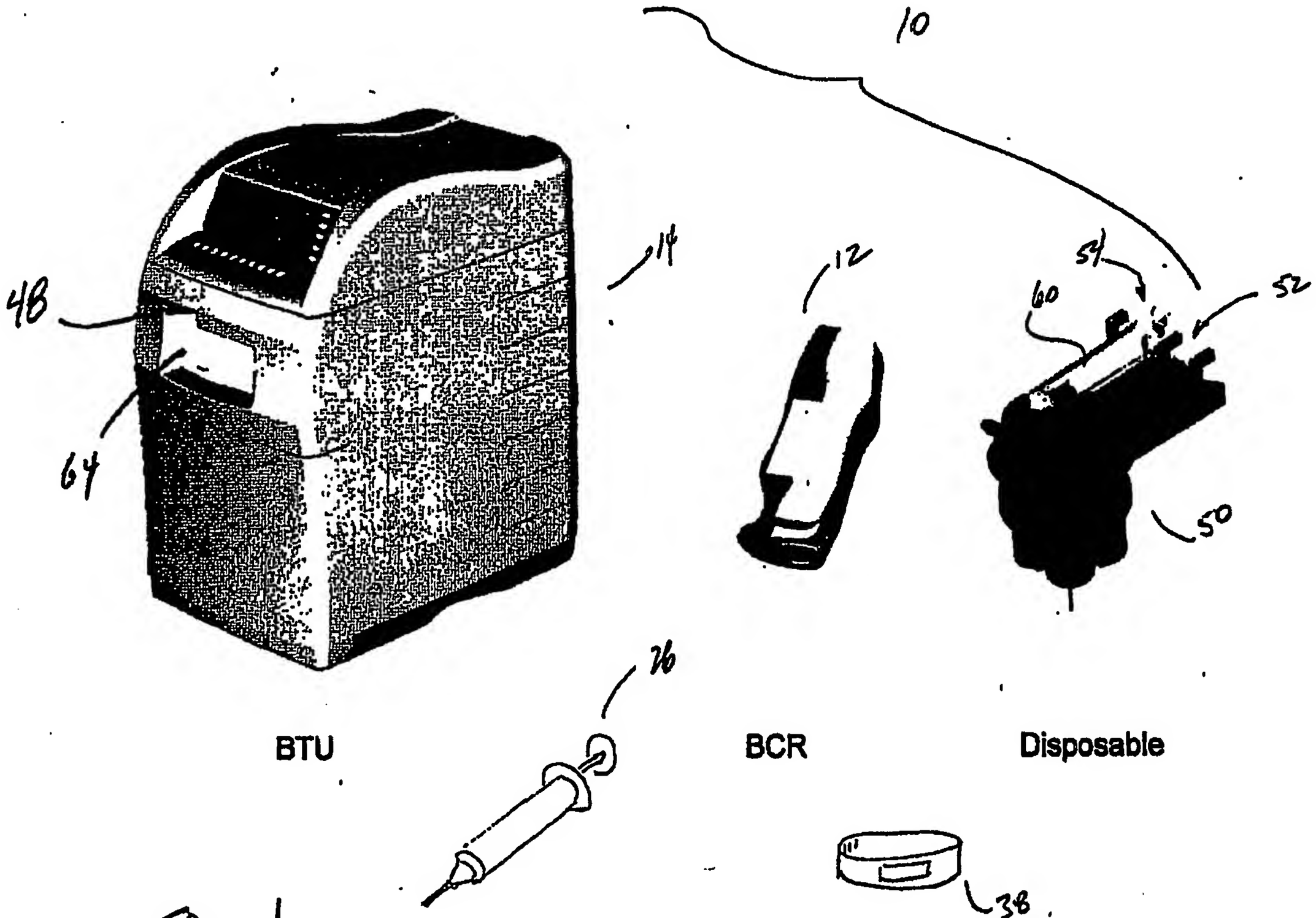


Fig. 1

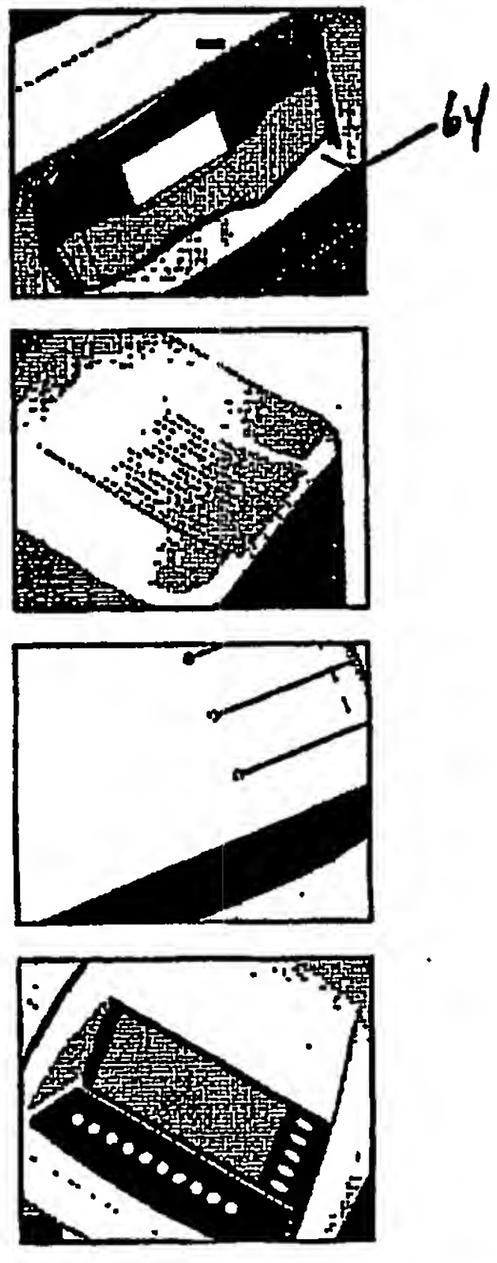
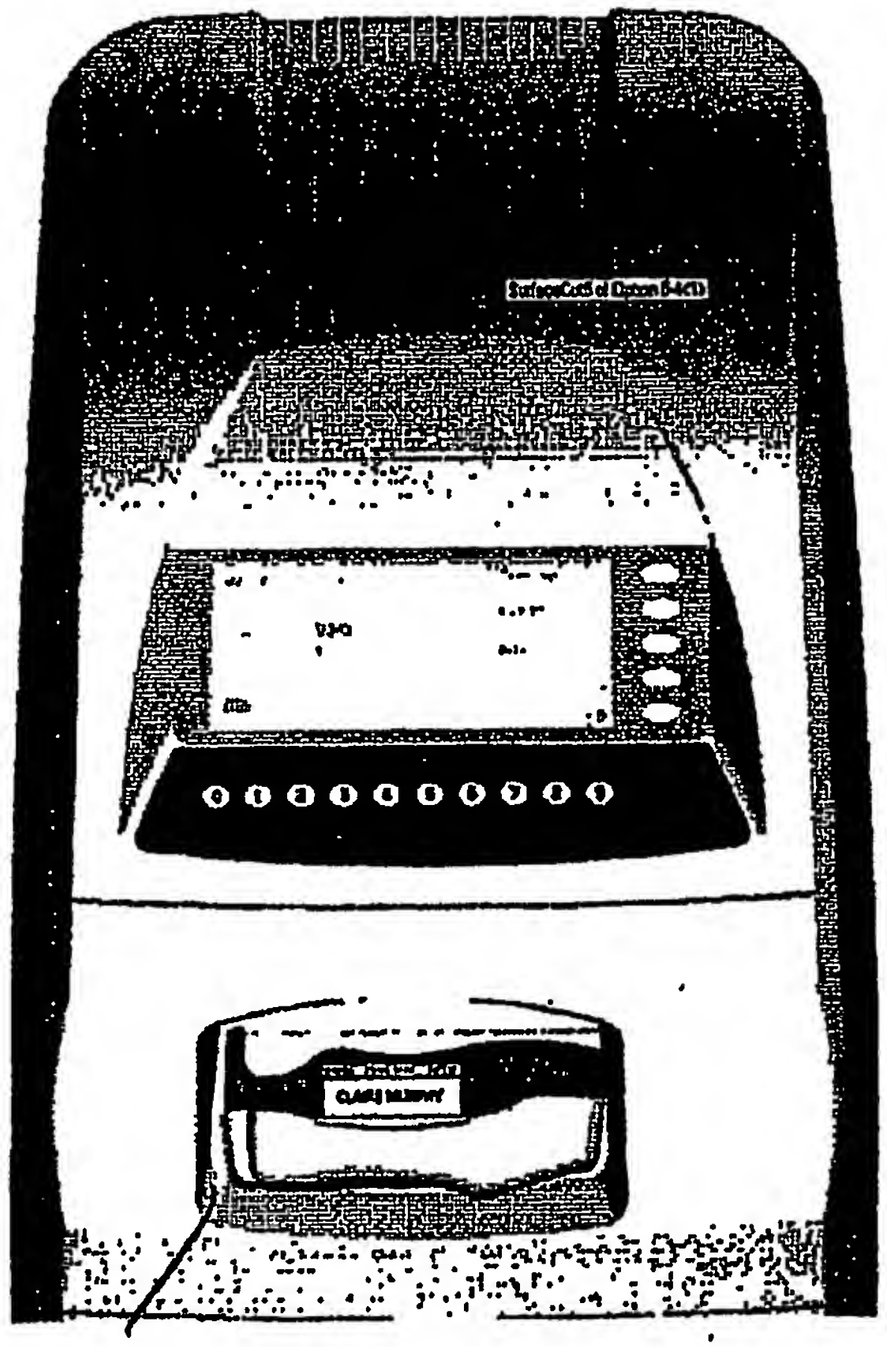


Fig. 2



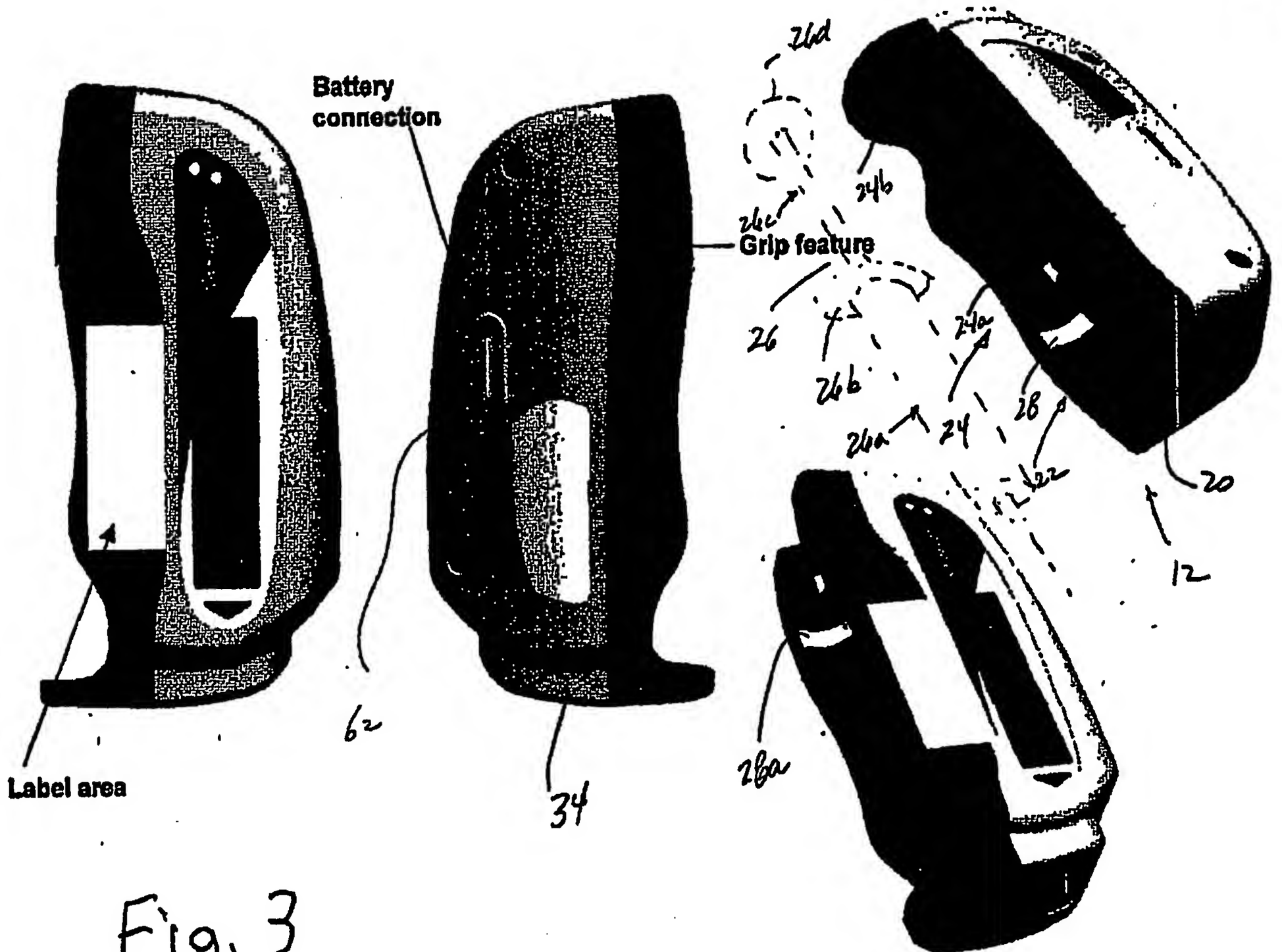

Battery connection
Grip feature
Label area
62
34
26d
26c
26b
26a
26
24b
24a
24
28
28a
22
20
12

Fig. 3

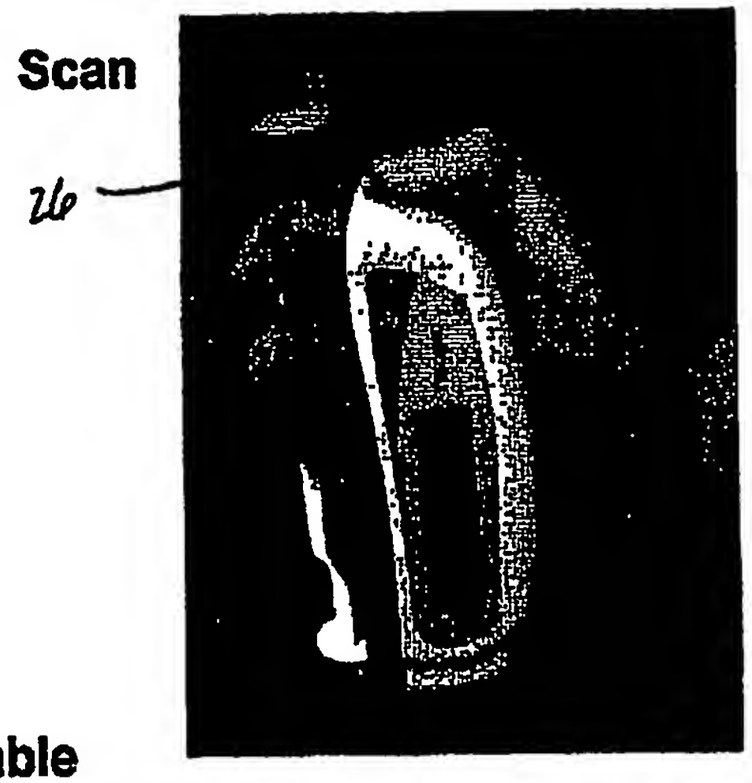


Fig. 4

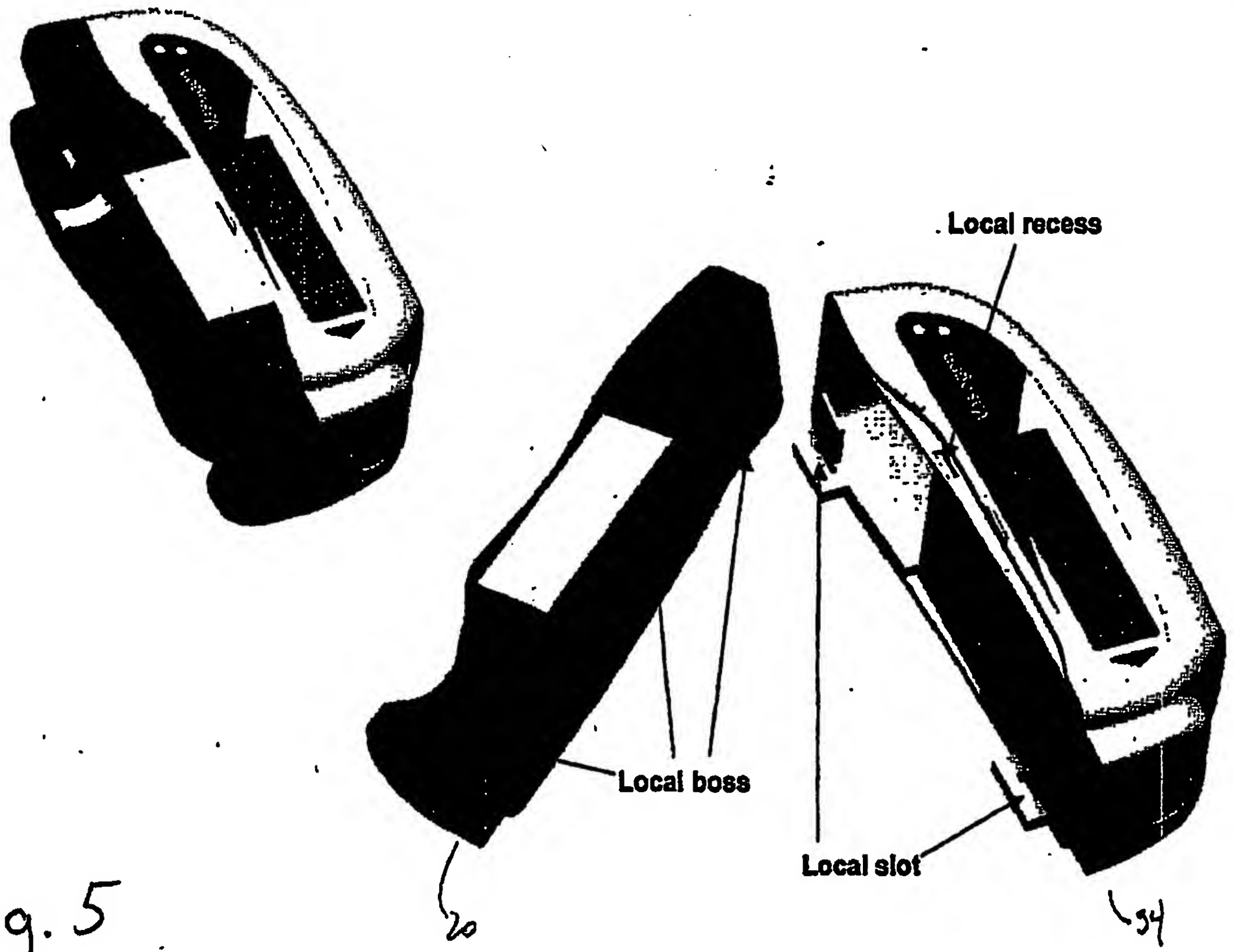


Fig. 5

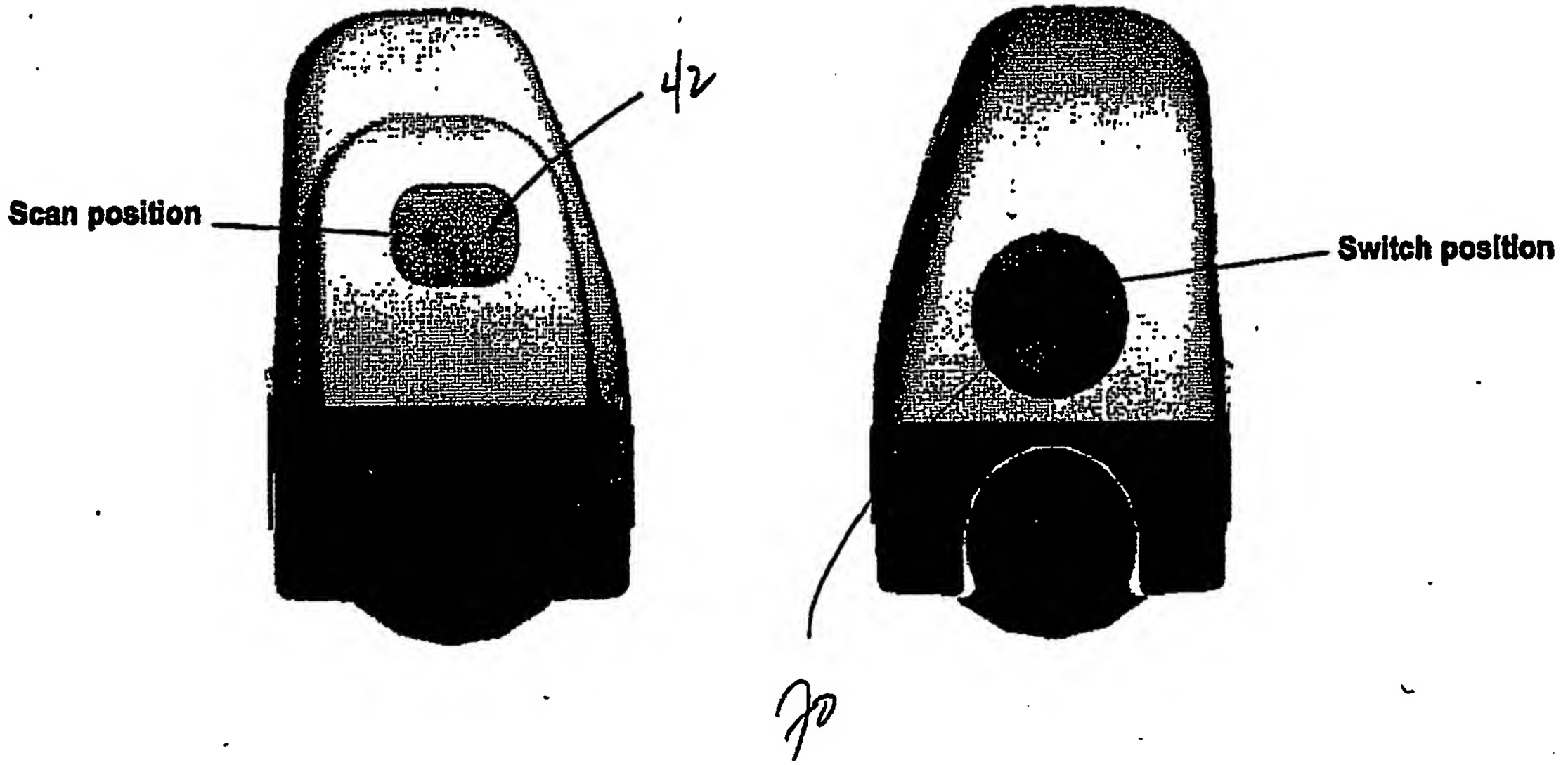


Fig. 6

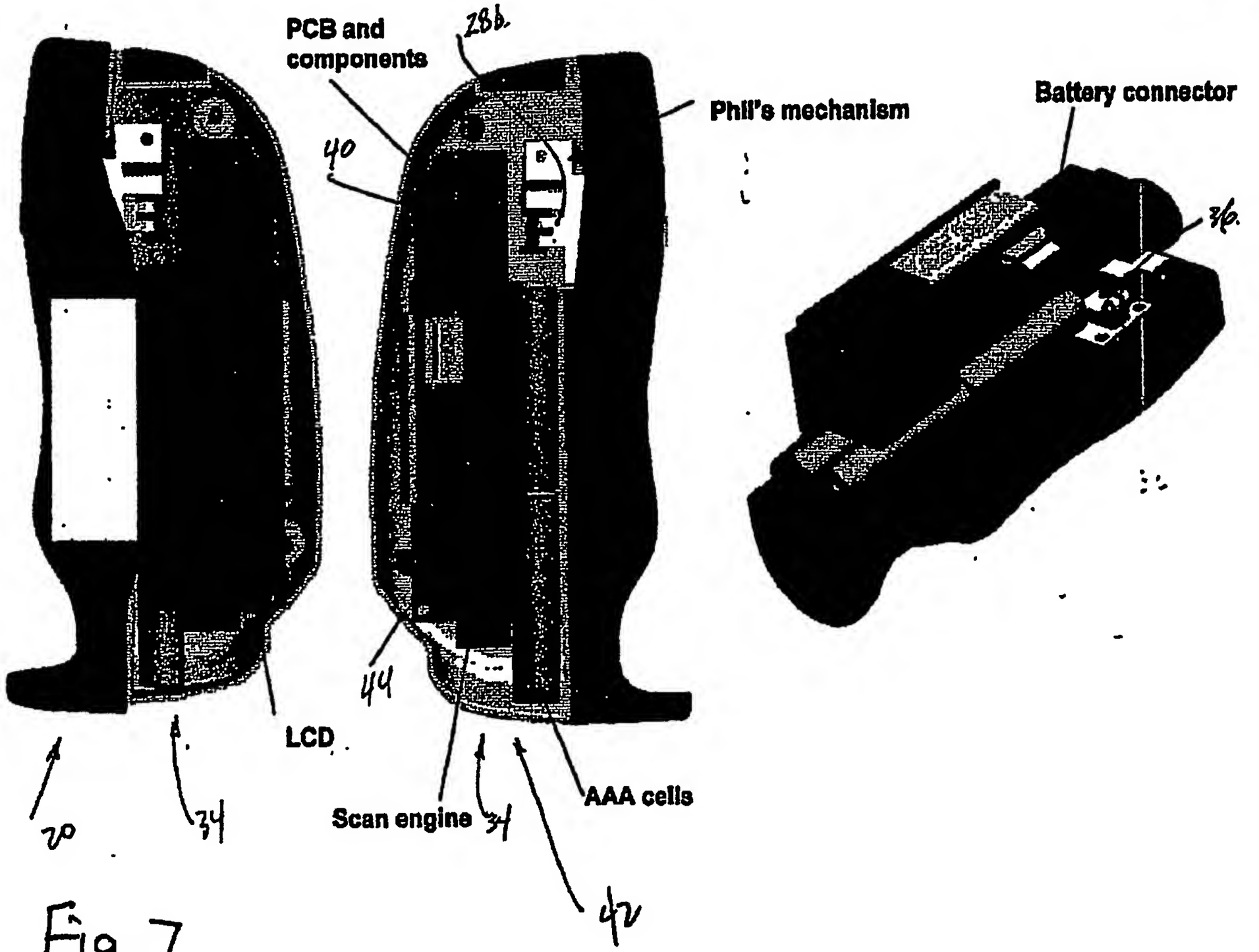

PCB and components
28b
Phil's mechanism
40
Battery connector
26
LCD
44
Scan engine
34
AAA cells
42
20
34

Fig. 7

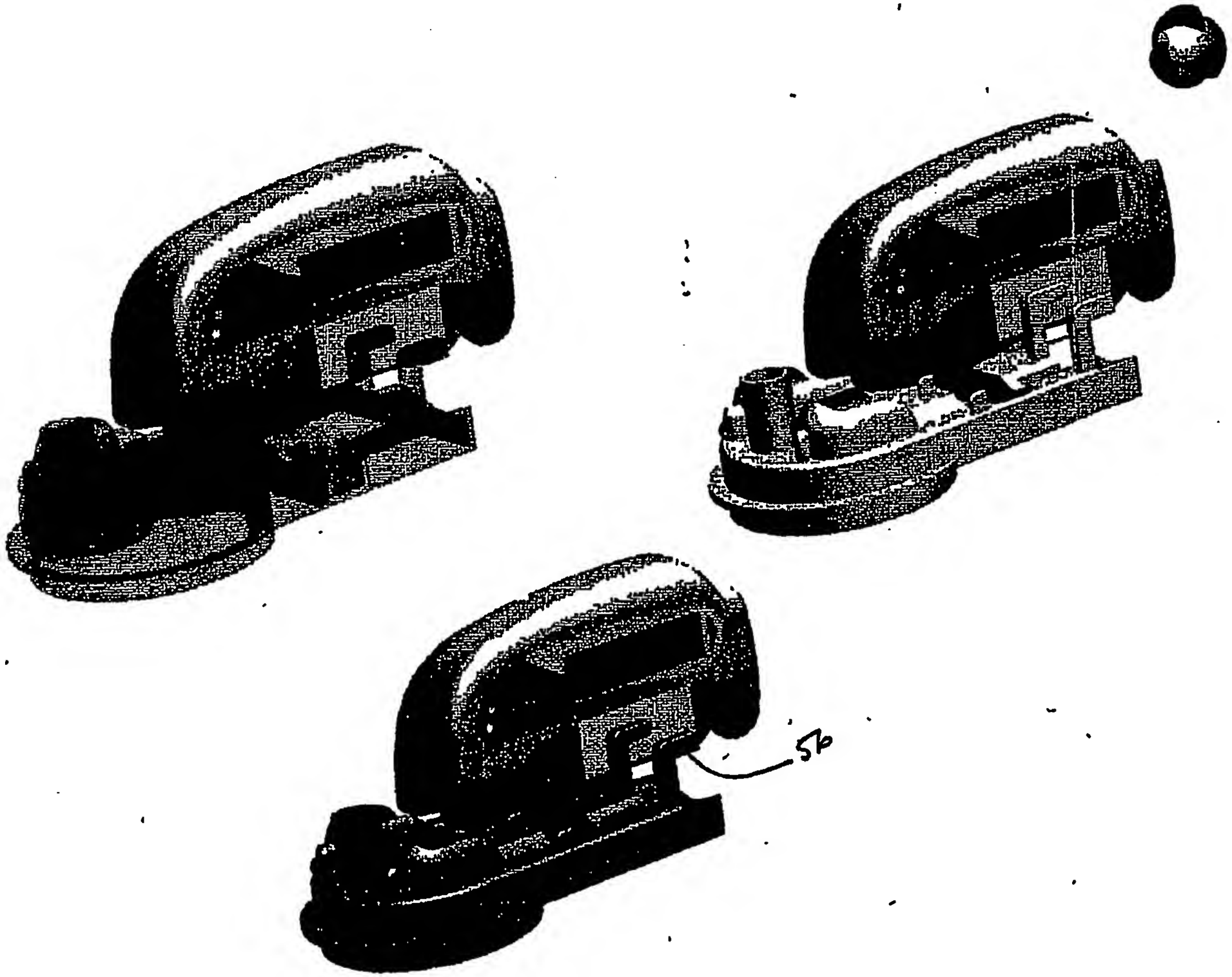


Fig. 8